Advanced Medical Solutions Ltd

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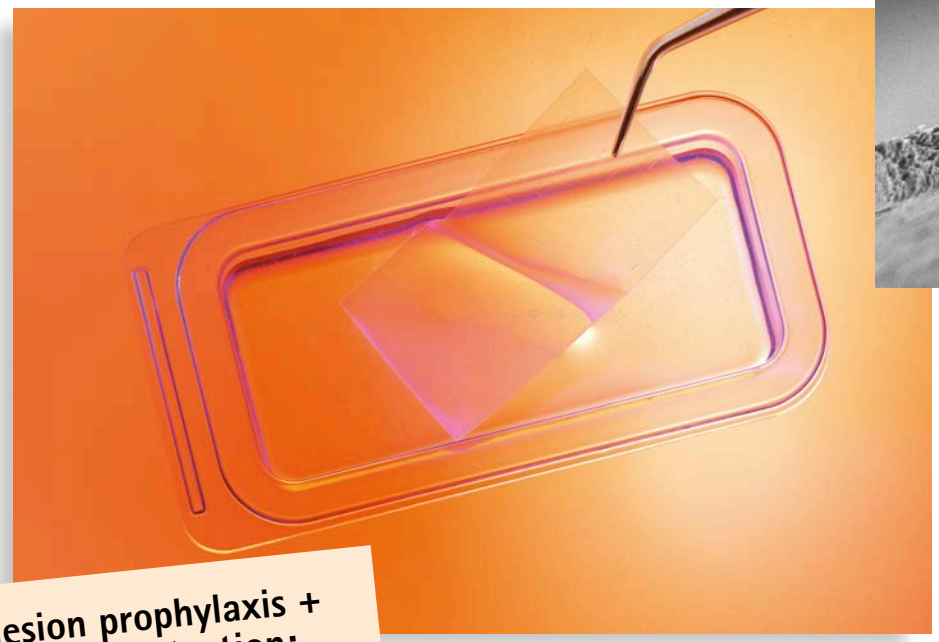
Maintaining function

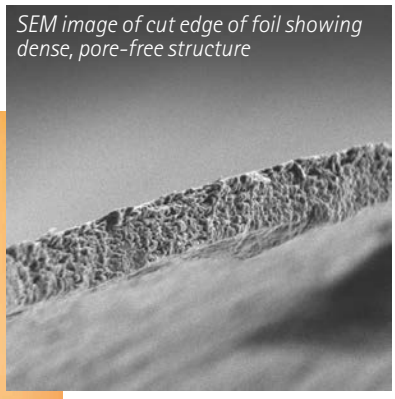
Concepts for hand surgery

RESORBA®

REPAIR AND REGENERATE

Unique: GENTA-FOIL *resorb*®





SEM image of cut edge of foil showing dense, pore-free structure

1 cm² of foil contains:
5.6 mg collagen of equine origin

4 mg gentamicin sulphate, equivalent to 2.20-2.86 mg gentamicin base

REF	Size	Package contents
GF 25	2.5 x 2.5 cm	1 foil / packaging unit
GF 255	2.5 x 5 cm	1 foil / packaging unit
GF 1010	10 x 10 cm	1 foil / packaging unit

Adhesion prophylaxis + antibiotic protection:
GENTA-FOIL *resorb*® is the only medical device to provide this combination of features.

Hand trauma and operations often lead to the formation of adhesions between the various tissue layers of the hand (e.g muscles, tendons and nerves). Even with minimally invasive procedures and optimal aftercare, development of adhesions in the suture and wound areas is often unavoidable. GENTA-FOIL *resorb*® is a transparent collagen foil that forms a temporary barrier between the functional structures. Thanks to the absorbability of its equine collagen, the foil can be left in place, no additional intervention being required to remove it. GENTA-FOIL *resorb*® does not induce any immune reaction or inflammation. As additional protection (useful where the risk of infection is high), the foil contains the aminoglycoside antibiotic gentamicin.

GENTA-FOIL *resorb*® Optimal characteristics for ensuring the success of hand operations:

- Absorbable
- Forms a temporary barrier
- Provides antibiotic protection
- Biocompatible
- Naturally crosslinked (without chemical additives)
- Easily shaped after brief moistening
- Stable structure and shape, yet flexible and stretchable
- Does not induce secretion

Illustration in original size

RESORBA®

Ensuring success, maintaining function

The objective of hand surgery is to promote wound repair and regeneration of all motor and sensory functions so as to restore the patient's fitness for work and improve his or her quality of life. However, successful post-traumatic care and surgical correction can be made difficult by undesirable developments such as:

- adhesions
- wound healing disturbances

Possible causes of adhesions:

- Foreign bodies (implants, suture material)
- Overheating and drying of the wound area
- Haematomas
- Infections
- Ischaemia

Traumatisation of tissue
↓
Inflammatory reaction
↓
Formation of a fibrin matrix
↓
Adhesions

Three powerful arguments

1. Adhesion prophylaxis

GENTA-FOIL *resorb*® provides a temporary barrier between the structural tissues of the hand during the critical phase of wound healing. As a result, the ability of the tissue layers to slide against each other is retained.
The dense structure of the absorbable foil provides an appropriate barrier during the period that is pathophysiologically relevant for the formation of adhesions.
In this way pain and restriction of movement, as well as the need for further operations to break down adhesions, can be avoided.
The collagen foil that forms the basis of GENTA-FOIL *resorb*® has been used successfully for many years as a biomatrix for temporary spinal or cerebral dura replacement and for dural reconstruction. This attests to the quality and biocompatibility of the product and its variants.

2. Wound regeneration and biocompatibility

GENTA-FOIL *resorb*® meets the various requirements of a **modern bioimplant:**

- **Absorbability**
- **Biocompatibility**
- **No immune reaction**
- **Inflammation-free wound healing**

The biocompatibility of GENTA-FOIL *resorb*® has been tested and confirmed in animal experiments (coating of tendons in rabbits, Figs. 1 and 2, see below).

3. Antibiotic protection

The role of GENTA-FOIL *resorb*® in providing mechanical protection and a separating layer is optimised by incorporation of an antibiotic to prevent infection. Gentamicin sulphate is an aminoglycoside antibiotic with broad-spectrum antibacterial activity.
Precisely because it can be applied locally after surgical procedures, GENTA-FOIL *resorb*® deals with the problem where it has arisen or must be overcome, without placing any additional burden on the organism.

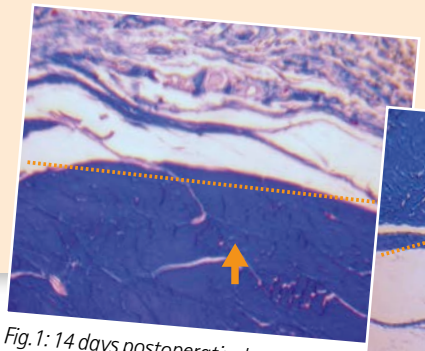


Fig. 1: 14 days postoperatively, normal pattern of cells at the edge of the tendon (arrow)

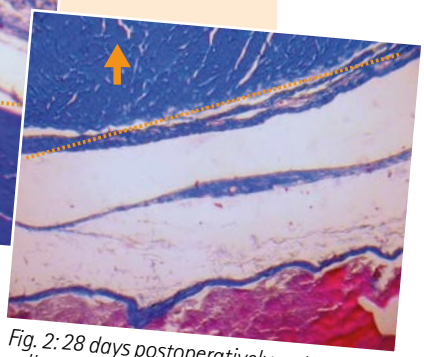


Fig. 2: 28 days postoperatively, pattern of cells around the tendon still normal (arrow)

RESORBA®

Innovation in clinical practice

Nail bed reconstruction

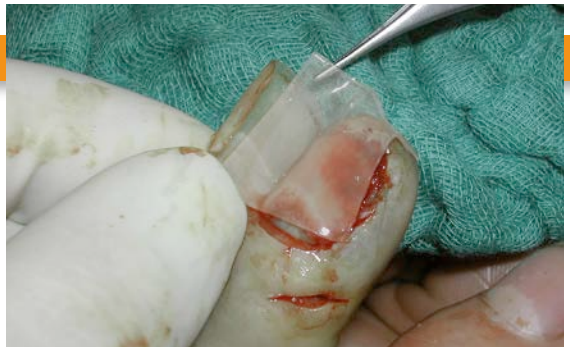
Hand injuries often involve damage to the fingernails and nail beds. Inadequate care of these structures can have serious consequences:

- cosmetically or functionally significant nail deformities
- infection of the distal phalanx (osteomyelitis)
- permanent difficulty with grip
- disturbances of sensation

GENTA-FOIL *resorb*® is applied as a temporary protective layer between the nail bed and the original nail plate, an artificial nail or a gauze bandage.

- **Rapid wound healing without inflammation**
- **Prevents nail bed from drying out**
- **Nail bed surface heals smoothly and evenly, even after reconstruction**
- **Prevents formation of haema-tomas between nail bed and nail plate**

"The nail beds never became dry and showed an outstanding tendency to heal." (Langer, Münster)



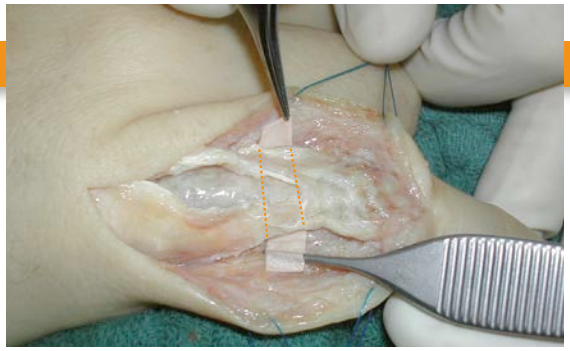
Tenolysis

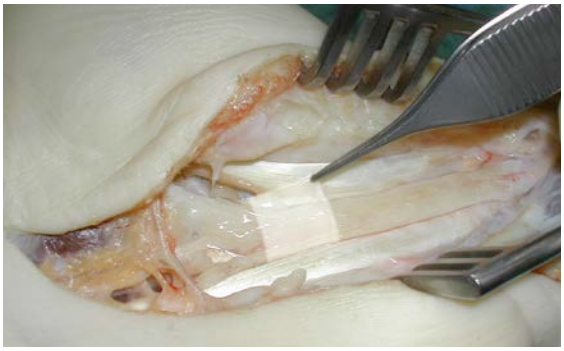
Even after correct primary care and suturing and competent secondary care, tendon and nerve injuries often lead to tendon adhesions that result in functional impairment and even stiffness of the affected finger. In many such cases surgical tenolysis is the only possibility for restoring full function.

GENTA-FOIL *resorb*® is inserted as a separating layer between bone and tendon or wrapped around a nerve. If necessary, the foil can be attached by means of individual sutures. Brief moistening with saline solution facilitates handling.

- **Adhesion prophylaxis to prevent the need for reoperation**
- **Mechanical protection of the area operated on**
- **Rapid wound healing without inflammation**

"Despite the fact that functional finger movement exercises were commenced by the second postoperative day, wound healing was undisturbed. This was true both of acute injuries and of secondary care." (Dönicke, Jena)





To assist visibility, GENTA-FOIL *resorb® is shown in colour in the illustration.*
All illustrations reproduced with kind permission of Dr. Langer, Münster.

RESORBA®

Suture material: loadbearing function

Tendon sutures

The objective of all operative efforts in tendon surgery is to achieve healing without formation of adhesions. This calls for:

- **atraumatic handling of the tendon**
- **preservation of the blood supply to the tendon**
- **early mobilisation of the suture**

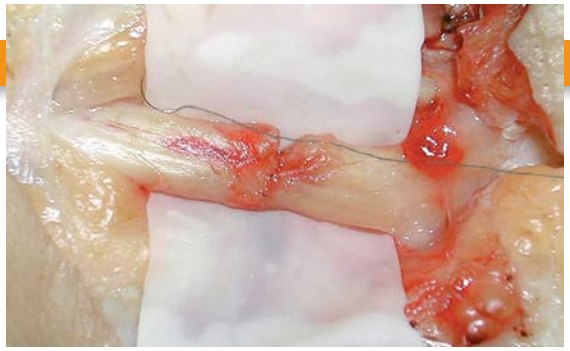
Tissue-sparing suturing techniques based on more detailed knowledge of the anatomy and physiology of tendons are being used ever more frequently. Use of core suture techniques in combination with finely adapted epitendinous RESORBA® sutures permits early loadbearing and leads to functionally optimal results.

Nerve sutures

Nerve reconstruction places very high demands on the surgeon and the material used:

- **Mastery of the surgical technique**
- **Indication-based choice of suture material to ensure atraumatic suturing and inflammation-free incorporation**

RESORBA® microsurgical suture materials are specially designed to satisfy these requirements.



GENTA-FOIL fixation

RESORBA® has developed special suture combinations for fixing GENTA-FOIL *resorb*®.

Brief moistening of the foil facilitates fixation.

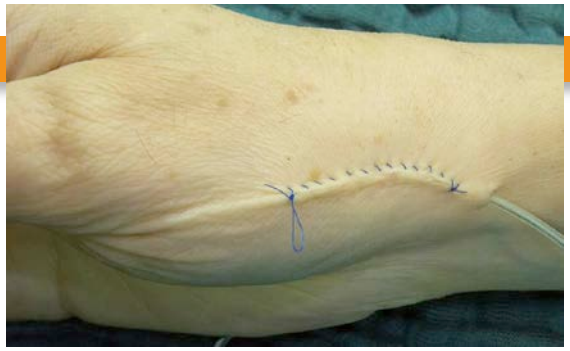
These sutures are incorporated rapidly and without inflammation and do not need to be removed.

Skin sutures

Finally, skin sutures should:

- **provide secure wound closure**
- **produce an aesthetically pleasing result**
- **allow painless suture removal**

RESORBA® supplies appropriate suture material for all suturing techniques.



RESORBA®

Successful product concepts ...

Adhesion prophylaxis + antibiotic protection:
GENTA-FOIL *resorb*® is the only medical device to provide this combination of features.
The need to refine surgical techniques and optimise the suture materials used to promote wound repair and regeneration of motor and sensory function are constant challenges for surgeons and medical device developers. In this regard increasing attention is being paid to the aesthetic result as perceived by the patient.

Suture material contributes to the success of treatment by providing:

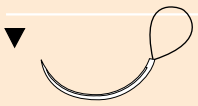
- **secure and atraumatic wound adaptation**
- **optimal support for wound healing**
- **satisfactory restoration of function and appearance**

RESORBA® suture materials are designed to meet the requirements of standard techniques and are now being extended to include special suture combinations for attaching GENTA-FOIL *resorb*®.

GENTA-FOIL *resorb*®

Collagen-gentamicin foil	GF 25	2.5 x 2.5 cm
Collagen-gentamicin foil	GF 255	2.5 x 5 cm
Collagen-gentamicin foil	GF 1010	10 x 10 cm

Tendon sutures

	REF	Description	Needle designation	USP	Thread length
	PN2151[1)]	PDO *RESORBA*™ violet	DSM11	6/0	45 cm
	7152	MOPYLEN® blue	DSM11	6/0	45 cm
	PN2154[1)]	PDO *RESORBA*™ violet	DSM13	5/0	45 cm
	PN2155[1)]	PDO *RESORBA*™ violet	DSM13	4/0	45 cm
	7155	MOPYLEN® blue	DSM13	6/0	45 cm
	7156	MOPYLEN® blue	DSM13	5/0	45 cm
	9152	SUPOLENE green	DSM13	5/0	45 cm
	9153	SUPOLENE green	DSM13	4/0	45 cm
	71511	MOPYLEN® blue	DSM16	4/0	45 cm
	71513	MOPYLEN® blue	DSM18	4/0	45 cm
	71514	MOPYLEN® blue	DSM18	3/0	45 cm
	PN21510[1)]	PDO *RESORBA*™ violet	DSM18	4/0	45 cm
	PN2149[1)]	PDO *RESORBA*™ violet	DS18	4/0	30 cm
	71447	MOPYLEN® blue	DS18	4/0	30 cm
	71448	MOPYLEN® blue	DS18	3/0	30 cm
	PN2081[1)]	PDO *RESORBA*™ violet	DRT18	4/0	45 cm
	7089	MOPYLEN® blue	DRT18	4/0	75 cm
	PN2255[1)]	PDO *RESORBA*™ violet	DRTM12	6/0	70 cm
	PN2256[1)]	PDO *RESORBA*™ violet	DRTM12	5/0	70 cm
	7258	MOPYLEN® blue	DRTM12	6/0	75 cm
	PN2091[1)]	PDO *RESORBA*™ violet	GR20	4/0	35 cm

RESORBA®

… for hand surgery

Micro sutures

	REF	Description	Needle designation	USP	Thread length
● ◡	50714N[1)]	NYLON black	DR4	10/0	10 cm
● ◡	5071N[1)]	NYLON black	DR5F	10/0	15 cm
	5072N[1)]	NYLON black	DR5F	9/0	15 cm
● ◡	5075N[1)]	NYLON black	DR6	9/0	15 cm
	5076N[1)]	NYLON black	DR6	8/0	15 cm

GENTA-FOIL fixation

▽ 	PB41503	GLYCOLON® violet	DSM13	5/0	45 cm
	PB41508	GLYCOLON® violet	DSM13	4/0	45 cm

Skin sutures

▽ 	88153	RESOLON® blue	DSM13	6/0	45 cm
	88154	RESOLON® blue	DSM13	5/0	45 cm
▽ 	88155	RESOLON® blue	DSM16	5/0	45 cm
	88156	RESOLON® blue	DSM16	4/0	45 cm
▽ 	88158	RESOLON® blue	DSM18	4/0	45 cm

Intracutaneous suture

▽ 	PB41502	GLYCOLON® undyed	DSM11	6/0	45 cm
▽ 	PB41504	GLYCOLON® undyed	DSM13	6/0	45 cm
	PB41505	GLYCOLON® undyed	DSM13	5/0	45 cm

RESORBA® sutures are adapted to the known suture techniques and are extended by special combinations to fixate GENTA-FOIL *resorb*®.

RESORBA®
➜ suture recommendations

PDO *RESORBA*™
monofilament, long-term absorbable
➜ Tendon sutures

GLYCOLON®
monofilament, short-term absorbable
➜ Intracutaneous suture
➜ GENTA-FOIL *resorb*® fixation suture

MOPYLEN®
monofilament, non-absorbable
➜ Tendon sutures

NYLON
monofilament, non-absorbable
➜ Nerve sutures

RESOLON®
monofilament, non-absorbable
➜ Skin suture

SUPOLENE
multifilament, coated, non-absorbable
➜ Tendon sutures

[1)] Product manufactured by:

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Email: sales@suturesindia.com
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